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10/518,450	12/20/2004	Eberhard Ammermann	5000-0111PUS1	7849
2292 7590 05/09/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040 0747			EXAMINER	
			SZNAIDMAN, MARCOS L	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1611	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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mailroom@bskb.com

	Application No.	Applicant(s)			
	10/518,450	AMMERMANN ET AL.			
Office Action Summary	Examiner	Art Unit			
	MARCOS SZNAIDMAN	1611			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>20 December</u> 2a)    This action is <b>FINAL</b> .    2b)    This  3)    Since this application is in condition for alloware closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-8 is/are pending in the application. 4a) Of the above claim(s) is/are withdrav 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-8 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine	r election requirement.				
10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the confidence of th	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
	animer. Note the attached Office	Action of ionin 10-132.			
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)  1) ☑ Notice of References Cited (PTO-892)  2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) ☑ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3 pages / 12/20/04.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	ate			

## **DETAILED ACTION**

This office action is in response to applicant's filing of December 20, 2004.

## Status of Claims

Claims 1-8 are currently pending and are the subject of this office action.

Claims 1-8 are presently under examination.

## **Priority**

The present application is a 371 of PCT/EP03/06890 filed on 06/30/2003, and claims priority to foreign application: GERMANY 10232751 filed on 07/18/2002.

#### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 provides for the use of "the compounds of formula I and II for preparing a mixture as in claim 1", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for controlling *Plasmopara viticola* in grapevines, does not reasonably provide enablement for all other phytopathogenic fungi. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is a scope of enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996). As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

- 1- the quantity of experimentation necessary,
- 2- the amount of direction or guidance provided,
- 3- the presence or absence of working examples,
- 4- the nature of the invention,
- 5- the state of the prior art,
- 6- the relative skill of those in the art,
- 7- the predictability of the art, and
- 8- the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping

that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

#### 1. The nature of the invention

Claims 5-7 recite a methodfor the controlling harmful fungi, comprising treating the harmful fungi with a mixture of either compound Ia or Ib and compound II in a synergistically effective amount.

# 2. The state and predictability of the art

Synergistic effects for combination of compounds are highly unpredictable. In fact there are no examples in the literature where two compounds that are biologically active against one target were predicted to act in a synergistic form. So far, the only way to determine synergy between two or more active substances is experimentally.

## 3. The relative skill of those in the art

The relative skill is generally that of an M.S. or Ph.D. in agrochemical sciences.

## 4. The breadth of the claims

Claims 5-7 claim to control every type of fungi with the mixtures of claim 1.

# The amount of direction or guidance provided and the presence or absence of working examples

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The specification provides data for controlling *Plasmopara viticola* in grapevine (see page 7). The specification provides no direction or guidance for controlling any other type of fungi.

# 6. The quantity of experimentation necessary

In the absence of previous examples in the prior art and in the absence of experimental evidence commensurate with the scope of the claims, how is the skilled in the art supposed to know which proportions of each compound to use for each type of fungi? This would require determining the optimum ratio and absolute amounts of compounds Ia or Ib and II, formulation into a dosage form, and subjecting into testing. This is undue experimentation given the limited guidance and direction provided by Applicants.

Accordingly, the inventions of claims 5-7 do not comply with the scope of enablement requirement of 35 U.S.C 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation with no assurance of success.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi et. al. (Proc. Br. Crop. Prot. Conf. – Pest and Diseases (1996) 1:21-26, cited by applicant) or Mercer et. al. (Proc. Br. Crop. Prot. Conf. – Pest and Diseases (1998) 1:319-326, cited by applicant) and Rohrbach et. al. (CAS accession number 1980:35984, corresponding to EP 4357).

Claims 1-4 recite a fungicidal mixture, comprising: 1) a phenylhydrazide I selected from the compounds Ia (RPA 407213) and Ib (DPX-JE874), and 2) the compound of formula II (dithianon) in a synergistically effective amount.

For claims 1-4, Joshi et. al. teach a fungicidal composition comprising DPX-JE874 for the treatment of *Plasmopara viticola* (see abstract and Table 2 on page 23), they also teach synergistic activity with other fungicides like cymoxanil (see table 3). For claims 1-7, Mercer et. al., teach a fungicidal composition comprising RPA 407213 for the treatment of *Plasmopara viticola* (see abstract), they also teach synergistic activity with other fungicides (see Tables 4-6 on pages 323 -324). Neither, Joshi et. al., or Mercer et. al. teach a fungicidal composition comprising dithianon. However, Rohrbach et. al. teach a fungicidal composition comprising dithianon for the treatment of *Plasmopara viticola* (see abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to combine two compositions (RPA 407213 or DPX-JE874, and dithianon) each of which is taught by the prior art to be useful for the same purpose (fungicidal compounds for the treatment of *Plasmopera viticola*), in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (see MPEP 2144.06). *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) claims to a process preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious. All this would result in the practice of claims 1-4 with a reasonable expectation of success.

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Claims 5-7 recite a methodfor the controlling harmful fungi, comprising treating the harmful fungi with a mixture of either compound Ia (RPA 407213) or Ib (DPX-JE874) and compound II (dithianon) in a synergistically effective amount.

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For claims 5-7, Joshi et. al. teach a method for the treatment of *Plasmopara viticola* with a fungicidal composition comprising DPX-JE874 (see abstract and Table 2 on page 23), they also teach synergistic activity with other fungicides like cymoxanil (see table 3). For claims 5-7, Mercer et. al., teach a method for the treatment of *Plasmopara viticola* with a fungicidal composition comprising RPA 407213 (see abstract), they also teach synergistic activity with other fungicides (see Tables 4-6 on pages 323 -324). Neither, Joshi et. al., or Mercer et. al. teach a method of treating *Plasmopara viticola* with a fungicidal composition comprising dithianon. However, Rohrbach et. al. teach a method for the treatment of *Plasmopara viticola* with a composition comprising dithianon(see abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to treat *Plasmopara viticola*, combining two compositions (RPA 407213 or DPX-JE874, and dithianon) each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (see MPEP 2144.06). *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) claims to a process preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be

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prima facie obvious. All this would result in the practice of claims 5-7 with a reasonable

expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to MARCOS SZNAIDMAN whose telephone number is

(571)270-3498. The examiner can normally be reached on Monday through Thursday 8

AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael P. Woodward can be reached on 571 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the Patent Application

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1000.

MLS April 16, 2008 /MP WOODWARD/

Supervisory Patent Examiner, Art Unit 1615